

REMARKS

Reconsideration of this application is respectfully requested.

Claim 25 has been amended to a generic claim. Claims 26-28 are new and are dependent upon claim 25. Claim 26 recites a purified recombinant DNA that hybridizes to the DNA of claim 17 under stringent conditions. Claims 27 and 28 recite the DNA of claims 17 and 18, respectively. Upon amendment, claims 17-28 are pending in this application with claims 17-22 allowed. No new matter enters by amendment.

Claims 23-25 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventors had possession of the claimed invention at the time the application was filed. Applicants traverse the rejection.

In *Enzo Biochem., Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 63 U.S.P.Q.2d 1609 (Fed. Cir. 2002), the Court of Appeals for the Federal Circuit was faced with an issue of direct relevance to the rejected claims this application, namely, the compliance of genus claims to nucleic acids based on their hybridization properties with the written description requirement of 35 U.S.C. § 112, first paragraph. Enzo's claims were directed to nucleic acids that selectively hybridized to a particular species of bacteria. 296 F.3d at 1321-22, 63 U.S.P.Q.2d at 1611. Applicant's claims 23, 24, and 26 are similarly directed to a DNA that hybridizes to a particular HIV-1 DNA under stringent conditions. The court provided guidance as to how to determine whether genus claims to nucleic acids based on their hybridization properties fulfill the written description requirement of 35 U.S.C. § 112, first paragraph:

The PTO has also provided a contrasting example of genus claims to nucleic acids based on their hybridization properties, and has determined

that such claims may be adequately described if they hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar. See *id.*, Example 9, at 35-37. Whether the disclosure provided by the three deposits in this case, coupled with the skill of the art, describes the genera of claims 1-3 and 5 is a fact question the district court did not address. On remand, the district court should determine, consistently with the precedent of this court and the PTO's Guidelines, whether one skilled in the art would consider the subject matter of claims 1-3 and 5 to be adequately described, recognizing the significance of the deposits and the scope of the claims.

296 F.3d at 1327-28, 63 U.S.P.Q.2d at 1615.

Thus, in *Enzo*, the Federal Circuit cited the PTO's Guidelines with respect to compliance of genus claims to nucleic acids based on their hybridization properties with the written description requirement of 35 U.S.C. § 112, first paragraph. This type of claim may be adequately described because the hybridization conditions may dictate that all species within the genus will be structurally similar.

Application of the analysis set forth in *Enzo* demonstrates that applicants' claims 23, 24 and 26 are adequately described because the recitations in applicants' claims dictate that all species within the claimed genus will be structurally similar. Similar to language in the claims at issue in *Enzo*, claims 23, 24 and 26 recite a DNA that hybridizes to the DNA of claim 17 under stringent conditions. As in *Enzo*, this recitation in the claims imposes a structural limitation on the claims, and dictates that all species within the claimed genus will be structurally similar to the DNA of claim 17. The Examiner has conceded that the DNA of claim 17 is fully described. Thus, according to the test set forth in *Enzo*, applicants' claims 23, 24 and 26 fulfill the requirements of 35 U.S.C § 112, first paragraph.

In addition, new claims 25, 27, and 28, do not recite "hybridization language" and obviate the rejection on this basis.

Applicants respectfully submit that this application is in condition for allowance. In the event that the Examiner disagrees, he is invited to call the undersigned to discuss any outstanding issues remaining in this application in order to expedite prosecution.


Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 18, 2004

By: _____


Salvatore J. Arrigo
Registration No. 46,063
Telephone: 202-408-4160
Facsimile: 202-408-4400
E-mail: arrigos@finnegan.com